CV-03-0349856 S	:	SUPERIOR COURT
	:	
MAREK ZAKRZEWSKI	:	
Plaintiff,	:	J.D. OF DANBURY
	:	
v.	:	AT DANBURY
	:	
PURDUE PHARMA, Inc.,	:	
PURDUE PHARMA, L.P.,	:	
THE PURDUE FREDERICK	:	
COMPANY, THE PURDUE	:	
PHARMA COMPANY	:	
Defendants.	:	OCTOBER 7, 2003

AMENDED COMPLAINT

COUNT ONE: (Retaliation for Protesting Unsafe Activities-Violation of C.G.S. § 31-51m)

1. The Plaintiff, Marek Zakrzewski, PhD, is a person who resides, and at all relevant times, resided in Danbury, Connecticut.

2. Defendant, Purdue-Pharma, Inc., upon information and belief, is a New York corporation with its principal place of business located in Stamford, Connecticut. It is the general partner of Defendant, Purdue-Pharma, LP.

3. Defendant, Purdue-Pharma, LP, upon information and belief, is a Delaware limited partnership with its principal place of business located in Stamford, Connecticut.

4. Defendant The Purdue Pharma Company is a Delaware general partnership with its principal place of business at 100 Connecticut Avenue, Norwalk, Connecticut.

5. Defendant The Purdue Frederick Company is a New York corporation with

its principal place of business at 100 Connecticut Avenue, Norwalk, Connecticut. At all times relevant hereto The Purdue Frederick Company was in the business of designing, testing, manufacturing, and selling and/or distributing OxyContin.

6. The Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 *et seq.* is the principal statute governing the manufacture and distribution of drug products within the United States.

7. In order to manufacture and distribute a drug for human use, a drug product manufacturer must submit a new drug application ("NDA") and receive approval from the FDA prior to distributing that drug product. 21 U.S.C. § 355(a). An NDA is submitted under penalty of false statement on form FDA 356h.

8. As set forth in 21 U.S.C. § 355(b)(1), the NDA process requires a drug product manufacturer to submit full reports to the FDA demonstrating that a drug is safe and effective. Additionally, and among other items, the drug product manufacturer must submit "(C) a full statement of the composition of such drug" and "(D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug."

9. The FDA requires that the chemistry, manufacturing and controls technical section ("CMC") of the NDA fully describe the composition, manufacture and specifications of the drug product and the drug substance, including physical and chemical characteristics, including particle size and stability. 21 CFR § 314.50(d)(1).

10. Under 21 U.S.C. § 356a and the regulations promulgated thereunder (21 CFR Part 314), a drug product manufacturer must notify the FDA about changes

discovered in the chemicals in the drug and the FDA must be given an opportunity to determine if the distribution of the drug should be suspended as a result of the discovered changes.

11. Only approved, unadulterated drugs can be sold. Under 21 U.S.C. § 351, a drug product is deemed to be adulterated if it differs from what was approved by the FDA for distribution.

12. The failure of a drug product manufacturer to comply with the regulations set forth in 21 C.F.R Parts 210 and 211 in the manufacture, processing, packing or holding of a drug shall render such drug adulterated. Included among these requirements are: 1) the examination and testing of drug substance samples to verify the identity of each component of a drug product; and 2) testing for conformity with all appropriate written specifications for purity, strength, and quality.

13. It is a criminal violation of the Food Drug and Cosmetics Act to: introduce or deliver for introduction into interstate commerce any food, drug, device, or cosmetic that is adulterated or misbranded (21 U.S.C. § 301(a)); and, submit a report to the FDA that is false or misleading in any material respect (21 U.S.C. § 301(y)).

14. OxyContin is the brand name of a 12 hour slow-release formulation of Oxycodone HCl manufactured and distributed by Defendants. Oxycodone HCl is recognized as a strong opioid and in analgesic potency, Oxycodone HCl is comparable to morphine. OxyContin and Oxycodone HCl are Schedule II controlled substances. OxyContin was approved by the FDA on December 12, 1995 based on the description of the chemical components of the drug submitted in Defendants' New Drug Application

(NDA).

15. Defendants have claimed in its advertisements of OxyContin that OxyContin can provide controlled delivery of the parent drug Oxycodone HCl over a 12 hour period.

16. The molecular structure of Oxycodone HCl effects the time it takes for the drug to cross the blood-brain barrier. This time to onset of effects is a critical factor in the addictive potential of a drug, as a substance which gives a quick and immediate high is more addictive to the brain than one which comes on gradually.

17. Upon information and belief, the NDA submitted by Defendants to the FDA for OxyContin:

a. recognized only one crystalline form of Oxycodone HCl utilized in the manufacture of OxyContin;

b. recognized only one crystalline form of stearyl alcohol, which is the chemical that houses the Oxycondone HCl in OxyContin, utilized in the manufacture of OxyContin;

c. did not address the existence of variant or polymorphic forms of Oxycodone HCl or stearyl alcohol or the methods or means of detecting such polymorphic forms as a part of the quality control process;

d. recognized only one specific particle size for Oxycodone HCl.

18. Upon information and belief, Defendants have submitted annual reports to the FDA in accordance with regulations but despite being required to inform the FDA of significant issues, omitted any mention of the variant forms of Oxycodone HCl and

stearyl alcohol and particle size differences of Oxycodone HCl discovered by Plaintiff, as more fully described below.

19. At no time subsequent to the approval of OxyContin, have Defendants submitted any supplemental information to the FDA addressing the existence of polymorphic forms of Oxycodone HCl or stearyl alcohol or the different particle sizes found in Oxycodone HCl or the efforts of Defendants to detect and measure these polymorphic forms and variations in particle size or assess the impact of these differences on the effect and duration of OxyContin.

20. In 1995, the FDA approved Defendants' NDA with respect to OxyContin based on Defendants' stated representations that only one form of Oxycodone HCl and stearyl alcohol would be utilized in the manufacture of OxyContin.

21. Plaintiff was hired as an Assistant Director by Purdue in July 2000.

22. In May, 2001, Plaintiff discovered that polymorphic forms of Oxycodone HCl were being supplied to Defendants and Defendants were utilizing these forms in the production of OxyContin. Plaintiff discovered that the polymorphic forms of Oxycodone HCl forms dissolved at differing rates of speed. Additionally, he discovered that the polymorphic forms of Oxycodone HCl were unstable and when exposed to increased humidity or the passage of time would continue to transmute into other polymorphic forms of Oxycodone HCl.

23. These polymorphs differed structurally from the form of Oxycodone HCl originally approved by the FDA for use in Defendants' NDA. The discovery of polymorphic forms of Oxycodone HCl constituted a "major change" pursuant to FDA

guidelines. Accordingly, and pursuant to 21 C.F.R. § 314.70, Defendants were required to immediately notify the FDA.

24. Despite knowing that the existence of polymorphic forms of drug substances and their control in the drug manufacturing process was important to the FDA, Defendants failed to implement any procedures or quality control techniques to detect the existence of such forms in drug substances purchased by Defendants and intended for use in the manufacture of OxyContin.

25. These polymorphic forms of Oxycodone HCl with variable dissolution speeds were used by Defendants in uncontrolled amounts in the production of OxyContin.

26. The use of a faster dissolving form of Oxycodone HCl from that which was approved by the FDA could dissolve more quickly into the human body than expected and cause overdosing and potentially lead to addiction. Alternatively, a slower dissolving form of Oxycodone HCl would not provide a patient with the anticipated pain relief. This could lead a patient to consume additional OxyContin and contribute to over dosage.

27. In May, 2001, Plaintiff and a scientist in his department prepared a report entitled “Physical Characterization of Oxycodone HCl” which showed that there were different forms of Oxycodone HCl and that these different forms had different dissolution rates. Plaintiff presented these findings to his direct superiors: Philip Goliber, Senior Director Pharmaceutical Analysis; and Philip Palermo, Vice President, Pharmaceutical Analysis.

28. Starting in July, 2001 and continuing until October, 2002, Plaintiff repeatedly presented his findings regarding the different forms of Oxycodone HCl and the different dissolution speeds to management at monthly meetings with managerial and executive level employees of Defendants. Present at many of the monthly meetings were members of Defendants' regulatory compliance department. Some of those officials who were present at said meetings were: Dennis Jurgens, Director Regulatory Affairs; James Kelly, Associate Director, Regulatory Affairs; Linda Camera, Associate Director, Regulatory Affairs; James Webb, Assistant Director, Regulatory Affairs; Theresa Muchnick, Vice President Quality Assurance; Ben Oschlack, Vice President, Product Development; Larry Huang, Senior Director, Product Development; Steven Howard, Director, Product Development; Robert Kupper, Vice President; Charles Hildrebrand, Vice President; Theresa Muchnick, Vice President, Quality Assurance; Robert Loewenstein, Director Quality Assurance; Glen van Buskirk, Vice President; Mark Chasin, Vice President; Ping Chen, Senior Director; Lea Lipschitz, Executive Director; Samuel Stoopak, Senior Director; and Shawn Wang, Senior Director.

29. Plaintiff continued presenting this data internally until he suffered a massive heart attack in October, 2002.

30. Following Plaintiff's discovery that polymorphic forms of OxyCodone HCl existed and were being utilized in the manufacture of OxyContin, Philip Goliber, Plaintiff's immediate superior, told Plaintiff that he was forbidden from producing any record of testing the dissolution properties of different forms of Oxycodone HCl.

31. During this time, Purdue was being sued by users of OxyContin who had

overdosed on and/or had become addicted to the drug. Plaintiff stated to his superiors that the tablets of OxyContin that were being made with the faster dissolving form of Oxycodone HCl may be causing overdoses and could lead to addiction. Plaintiff was ordered by Goliber to never talk about his concerns again.

32. Plaintiff protested management's decision to forbid further testing and told his superiors that the FDA should be notified of the existence of the different forms of Oxycodone HCl. Indeed, Plaintiff specifically told management that FDA regulations required that the polymorphs that he discovered be tested and reported to the FDA in accordance with FDA requirements governing supplements and other changes to an approved application (21 C.F.R. § 314.70) and industry guidance issued by the FDA which appears at 65 Fed. Reg. 83046.

33. Plaintiff presented management with a copy of 65 Fed. Reg. 83046 which set forth the testing steps needed to be taken when polymorphisms are discovered. Plaintiff discussed these requirements at said monthly meetings.

34. Management forbade Plaintiff from continuing with the testing steps set forth in the 65 Fed Reg. 83046.

35. During this period, in the summer of July, 2001, the FDA requested testing regarding the particle size of Oxycodone HCl from Defendants because it had been notified that the dissolution results of OxyContin produced at Defendants' New Jersey facility varied.

36. Particle size influences dissolution speeds of Oxycodone HCl. Smaller particles dissolve faster than bigger particles; therefore, particle size needs to be

controlled in order to control the dissolution speed of a drug.

37. Variability in particle size of lots used in the production of OxyContin may cause some of the Oxycodone HCl in some of the lots to dissolve faster than others, potentially leading to overdose and addiction.

38. Plaintiff and the scientists in his department measured the particle size of the lots of Oxycodone HCl used at the New Jersey facility and discovered that the measurement method being used by Defendants did not accurately capture the different sizes of Oxycodone HCl particles. They issued reports entitled “Proposal for the Particle Size Specification for Oxycodone HCl Based on Laser Light Scattering” in December, 2001 and another report entitled “Determination of the Particle Size of Oxycodone HCl Using Laser Light Scattering Doc No. 1306-2002-0092” which reflected their conclusions.

39. Plaintiff developed a new method to measure particle size and proposed new tighter particle size specifications as requested by the FDA.

40. Plaintiff proposed testing the different forms of Oxycodone HCl that Defendants were using in the production of OxyContin by producing tablets of OxyContin with the different forms which dissolved at different rates of speed. Then Defendants could determine whether or not some tablets of OxyContin could dissolve faster than others depending on which form of Oxycodone HCl was present in a particular tablet.

41. Goliber told Plaintiff that he was not allowed to perform said tests and Defendants would not adopt tighter particle size specifications. Further, Goliber

ultimately also forbade Plaintiff from communicating with the regulatory department within the company regarding his findings and forbade him from including in any written report his findings regarding the effect of different particle sizes on dissolution rates and the dissolution rates of the different forms of Oxycodone HCl.

42. Goliber told Plaintiff that Defendants did not want any record of testing done on Oxycodone HCl. This directive was issued in order to avoid the creation of documentation which could be subpoenaed or would need to be turned over to the FDA.

43. Defendants did not inform the FDA that the method for measuring particle size identified in the NDA was less accurate than other methods and that it had developed a more accurate particle size testing procedure.

44. Plaintiff advocated strongly for further testing in order to ensure that OxyContin, as it was being manufactured, was safe for public use.

45. Oxycontin, is one of the most profitable drugs, if not the most profitable drug, for Defendants.

46. Defendants are facing several law suits that allege that patient addiction to Oxycodone HCl is through use of OxyContin.

47. In or about August, 2001, Plaintiff also discovered that different forms of the chemical stearyl alcohol were being utilized in the manufacture of OxyContin. Defendants use stearyl alcohol as an excipient in the formulation of the OxyContin.

48. On or about August 28, 2001, Plaintiff reported to management that different forms of stearyl alcohol may have different properties and may affect the dissolution characteristics of OxyContin. A scientist in his department, Kelly Hadden,

prepared a report entitled “Physical Characterization of Stearyl Alcohol” on said date regarding these findings on stearyl alcohol and concluded that stearyl alcohol “is a mixture of at least two different polymorphs.”

49. Management refused to accept this report and ordered another report to be issued stating that there was only one form of stearyl alcohol present in the production material. Said report was entitled “Stearyl Alcohol Anaslyis” and was issued on January 16, 2002 and was signed by another scientist, Anna Razynska, who had not performed the tests.

50. The FDA’s approval for Defendants to market OxyContin was based on Defendants’ representations that there was one form of Oxycodone HCl and one form of stearyl alcohol utilized in the production of OxyContin.

51. When different forms of Oxycodone HCl and stearyl alcohol were discovered, Defendants refused to follow the testing steps set forth by the FDA in 65 Fed Reg. 83055 to determine the effect of these polymorphs on OxyContin.

52. Defendants refused to perform these required tests and failed to inform the FDA regarding these discoveries because they knew or suspected that the FDA would suspend the approval for Defendants to sell OxyContin.

53. Defendants also knew that they were not authorized to sell OxyContin which deviated from the manufacturing specifications contained in the approval drug application. By failing to follow appropriate quality control requirements as well as utilizing unapproved drug substances in the production of OxyContin, Defendants manufactured an adulterated drug in violation of the federal regulations.

54. Management's position contravened FDA regulations including those under 65 Fed. Reg. 83,041 and 64 Fed. Reg. 65,716 which directs investigation of product safety, performance and efficacy in case another form of a drug substance, having different dissolution properties, was found.

55. Although Plaintiff had been forbidden to test the dissolution rate of the different forms of Oxycodone HCl, at his request, he was allowed to work on perfecting a test to measure dissolution rates of different forms of chemicals. Plaintiff was allowed to use the test on an abandoned drug. Plaintiff perfected the dissolution test and was about to test it on Oxycodone HCl, even without management approval, when, in July 2002, as a result of Plaintiff voicing his concerns and speaking out about the need for additional testing, and because Plaintiff was about to test the dissolution rates of the different forms of Oxycodone HCl, Defendants demoted Plaintiff. Defendants stripped Plaintiff of his title and all of his supervisory responsibilities and reduced his title to Senior Research Fellow.

56. As a pretext, Defendants alleged that Plaintiff was being demoted because he lacked adequate supervisory skills.

57. In the fall of 2002, because of the intense pressure Defendants placed upon Plaintiff to keep his findings silent and not disclose any negative information, Plaintiff suffered serious physical problems.

58. Feeling the pressure to commit fraud and remain quiet, Plaintiff became depressed and was forced to seek medical treatment and to take medication.

59. The work atmosphere became so intense and stressful, that Plaintiff

suffered a severe heart attack in October 2002 and was hospitalized for six days and bedridden for another seven days.

60. Plaintiff is still recovering from the effects of the heart attack and has not been able to return to work since the heart attack.

61. Plaintiff's heart pumping capacity is at 30% and consequently prevents him from walking at a normal pace.

62. Plaintiff had a pace maker and a defibrillator implanted in him.

63. He continues to suffer chest pains that prohibit him from performing all of his daily activities.

64. In April 2003, Plaintiff informed the FDA of the potential safety problems with OxyContin and the inadequacy of the testing being performed by Defendants.

65. The FDA informed Plaintiff that it was performing an investigation of Defendant's Rhode Island facility. Plaintiff told the FDA to investigate the different forms of Oxycodone HCl that were being produced at the facility.

66. In May 2003, knowing that Plaintiff had complained to the FDA, Defendants fired Plaintiff for raising and voicing concerns about Defendants' violations of FDA regulations and the health risks associated with OxyContin, one of Defendants' most profitable drugs.

67. Because Plaintiff reported Defendants' illegal practices both internally and to the FDA, Defendants fired him.

68. Although Defendants knew of Plaintiff's fragile psychological and physical health, Defendants caused Plaintiff emotional distress by terminating him unexpectedly

and continuing to harass him by encouraging others to take credit for publications and reports that he generated.

69. Defendants have tried to diminish Plaintiff's scientific achievements, which are a measure of his job adequacy, thus decreasing his ability to pursue other jobs in the future.

70. As a result of Defendants' actions, Plaintiff suffered, and still suffers, serious physiological and psychologically effects.

71. Plaintiff was, and still is, being treated by a cardiologist and a psychiatrist. Plaintiff is still taking various medications for his mental and physical problems.

72. By the above acts, Defendants violated C.G.S. § 31-51m.

73. As a result of the Defendants' actions, Plaintiff has suffered, and continues to suffer, financial damages and emotional distress.

COUNT TWO: (Retaliation for Exercising Right of Free Speech- Violation of C.G.S. § 31-51q)

1-71. Paragraphs 1 through 71 of Count One are hereby made paragraphs 1 through 71 of this Count Two as if fully set forth.

72. By their actions, stated herein above, Defendants violated C.G.S. § 31-51q.

73. As a result of the Defendant's actions, Plaintiff has suffered, and continues to suffer, financial damages and emotional distress.

COUNT THREE: (Common Law Wrongful Discharge)

1-71. Paragraphs 1 through 71 of Count One are hereby made paragraphs 1 through 71 of this Count Three as if fully set forth.

72. By their actions stated herein above, Defendant Purdue wrongfully terminated Plaintiff in violation of public policy.

73. The public policies which were violated are reflected in the laws and regulations set forth above.

74. As a result of the Defendant's actions, Plaintiff has suffered, and continues to suffer, financial damages and emotional distress.

COUNT FOUR : (Intentional Infliction of Emotional Distress)

1-71. Paragraphs 1 through 71 of Count One are hereby made paragraphs 1 through 71 of this Count Four as if fully set forth.

72. By their actions stated herein above, Defendant Purdue intentionally inflicted emotional distress upon Plaintiff.

73. As a result of the Defendant's actions, Plaintiff has suffered, and continues to suffer, financial damages and emotional distress.

COUNT FIVE: (Negligent Infliction of Emotional Distress)

1-71. Paragraphs 1 through 71 of Count One are hereby made paragraphs 1 through 71 of this Count Five as if fully set forth.

72. By their actions stated herein above, Defendant Purdue negligently inflicted emotion distress upon Plaintiff.

73. As a result of the Defendant's actions, Plaintiff has suffered, and continues to suffer, financial damages and emotional distress.

WHEREFORE, Plaintiff prays for:

1. Compensatory damages;

2. Punitive damages;

3. Attorney's fees and costs of this action;

4. Interest; and

5. Such other relief as this Court deems necessary and proper.

THE PLAINTIFF,

By:_____

Victoria de Toledo, Esq.
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1458 Bedford Street
Stamford, CT 06905
Tel. No.: (203) 325-8600
Juris No. 106056

CERTIFICATION

This is to certify that on this 7th day of October 2003, a copy of the foregoing was sent via regular mail to the following:

Margaret L. Strange
Jackson Lewis LLP
55 Farmington Ave.
Suite 1200
Hartford, CT 06105-3789

_____
Victoria de Toledo